

REMARKS

Claims 1-7 and 9-36 are pending in this application. Claims 12-20 and 33-36 have been cancelled as a result of the restriction requirement. Claims 1, 2, 21 and 26 have been amended. No new matter has been added. Thus, claims 1-7, 9-11 and 21-32 will be pending after entry of this Amendment. Reconsideration of the claims is respectfully requested.

Examiner Interview

The Applicants representative (John Gatz) would like to thank Examiner Salzman for the interview conducted on February 1, 2010. We discussed the applied references and independent claims 1 and 21. The Applicant stated that a written response would be filed discussing the same.

Election/Restriction

The Applicants are affirming the election of group 1 (claims 1-7, 9-11 and 21-32). Claims 12-20 and 33-36 (group 2) are being cancelled without prejudice as a result of the restriction requirement.

Claim Objection

Claim 26 is objected to under 37 CFR 1.75(c) as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 26 has been amended and, thus, the claim objection should be withdrawn.

35 U.S.C. § 102/103 Rejections

Independent Claim 1

Amended claim 1 recites a mediator, and “an oxidizable species as an internal reference, the oxidizable species being different than the mediator species and having different redox potentials.” The present invention is advantageous because “[s]ince the internal reference concentration is fixed, the calibration scope of the sensor will only depend on the sensor response for glucose while the intercept will depend on the added amount of the internal reference. In [o]ther words, the internal reference will only offset the intercept and will not

change the calibration scope.” Page 4, lines 9-13 of the patent application. The applied references of U.S. Patent No. 6,565,738 to Henning (“Henning”) and U.S. Patent Publication No. 2001/0052470 to Hodges et al. (“Hodges”) do not disclose, teach or suggest such “an oxidizable species as an internal reference, the oxidizable species being different than the mediator species and having different redox potentials” as recited in claim 1.

Rather, Henning discloses using a mediator (ferricyanide), which is oxidized by non-electrochemically active species (GLOX) that result in the reduction of ferricyanide to ferrocyanide. Col. 13, lines 15-50 of Henning. The ferrocyanide is then re-oxidized to ferricyanide when it reacts with the working electrode. Col. 13, lines 50-53 of Henning. Ferrocyanide and ferricyanide have the same redox potential. Thus, it is clear that Henning does not disclose, teach or suggest oxidizable species being different than the mediator species and having different redox potentials.

Similarly, Hodges discloses using a mediator (ferricyanide) that reacts and forms a product ferrocyanide. Paragraph 9 of Hodges. Hodges discloses that after the reaction is complete, the concentration of ferrocyanide indicates the initial concentration of glucose. *Id.* Thus, it is clear that Hodges does not disclose, teach or suggest oxidizable species being different than the mediator species and having different redox potentials.

Therefore, claim 1 is not anticipated by or rendered obvious over Hodges or Henning. Thus, claim 1 should be in a condition for allowance.

Dependent Claims 2-7, 9-11

To address further deficiencies in either Hodges or Henning, the Office Action has applied additional references (U.S. Patent No. 5,520,786 to Bloczynski (“Bloczynski”) and U.S. Publication No. 2004/0245121 to Nagakawa (“Nagakawa”) to selected claims. However, neither Bloczynski nor Nagakawa addresses the above noted deficiencies in Hodges and Henning. Specifically, neither Bloczynski nor Nagakawa discloses, teaches or suggests oxidizable species being different than the mediator species and having different redox potentials. Thus, dependent claims 2-7 and 9-11 are not anticipated by or rendered obvious over Hodges, Henning, Bloczynski, Nagakawa or any combination thereof for at least the reasons discussed above in claim 1.

Additionally, several dependent claims recite additional features that are not present in the applied references. For example, claim 2 recites “wherein said internal reference is a reduced form of a reversible redox couple that has a higher redox potential than that of said mediator” and claim 4, which is dependent on claim 3, recites an internal reference comprising ferrocyanide with a mediator comprising 3-phenylimino-3H-phenothiazine.

Therefore, claims 2-7 and 9-11 should be in a condition for allowance.

Independent claim 21

Amended claim 21 recites a method of forming and placing a reagent mixture and includes, inter alia, “forming a batch of reagent mixture by adding an enzyme, adding a mediator and adding an oxidizable species, the added oxidizable species being added separately from the mediator”. The applied references of Henning and Hodges do not disclose, teach or suggest such a feature.

Rather, Henning discloses using a mediator (ferricyanide), which is oxidized by non-electrochemically active species (GLOX) that result in the reduction of ferricyanide to ferrocyanide. Col. 13, lines 15-50 of Henning. The ferrocyanide is then re-oxidized to ferricyanide when it reacts with the working electrode. Col. 13, lines 50-53 of Henning. Similarly, Hodges discloses using a mediator (ferricyanide) that reacts and forms a product ferrocyanide. Paragraph 9 of Hodges. Hodges discloses that after the reaction is complete, the concentration of ferrocyanide indicates the initial concentration of glucose. *Id.* Neither Henning nor Hodges discloses adding the oxidizable species separately from the mediator.

Therefore, claim 21 is not anticipated by or rendered obvious over Hodges or Henning. Thus, claim 21 should be in a condition for allowance.

Dependent Claims 22-32

To address further deficiencies in either Hodges or Henning, the Office Action has applied additional references Bloczynski and Nagakawa to selected claims. However, neither Bloczynski nor Nagakawa addresses the above noted deficiencies in Hodges and Henning. Specifically, neither Bloczynski nor Nagakawa discloses, teaches or suggests adding the oxidizable species separately from the mediator. Thus, dependent claims 22-32 are not

anticipated by or rendered obvious over Hodges, Henning, Bloczynski, Nagakawa or any combination thereof for at least the reasons discussed above in claim 21.

Additionally, several dependent claims recite additional features that are not present in the applied references. For example, claim 25 recites “wherein said internal reference and said mediator are oxidized at a first voltage potential and only said mediator is oxidized at a second voltage potential, said second voltage potential being less than said first voltage potential” and claim 26 “wherein said internal reference and said mediator are oxidized at a first voltage potential and only said mediator is oxidized at a second voltage potential, said second voltage potential being higher than said first voltage potential.”

Therefore, claims 22-32 should be in a condition for allowance.

Conclusion

The Applicants submit that the claims are in a condition for allowance and action toward that end is earnestly solicited. The Commissioner, however, is authorized to deduct the one month extension fee of \$130.00 and any other fees (except the payment of the issue fee) from Nixon Peabody Deposit Account No. 50-4181, Order No. 247082-000168USPX.

Respectfully submitted,

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